FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
March 21, 2013

DRAFT AGENDA

The committee will discuss new drug application (NDA) 204442, PROBUPHINE (buprenorphine hydrochloride and ethylene vinyl acetate) subdermal implant, submitted by Titan Pharmaceuticals, Inc., and its safety and efficacy for the proposed indication of maintenance treatment of opioid dependence.

8:00 a.m.	**CALL TO ORDER AND INTRODUCTION OF COMMITTEE**	**Edward C. Covington, MD** Acting Chairperson, PDAC
8:05 a.m.	**CONFLICT OF INTEREST STATEMENT**	**Minh Doan, PharmD** Acting Designated Federal Officer, PDAC
8:10 a.m.	**FDA INTRODUCTORY REMARKS**	**Celia Winchell, MD** Clinical Team Leader Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODEII) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**SPONSOR PRESENTATIONS**	**TITAN PHARMACEUTICALS, INC.**
	Introduction	**Marc Rubin, MD** Executive Chairman Titan Pharmaceuticals, Inc.
	Background and Medical Need	**Andrea Barthwell, MD, FASAM** Former Deputy Director of Demand Reduction Office of National Drug Control Policy (ONDCP) Founder and CEO of the Two Dreams Treatment System
	Clinical Efficacy	**Kate Glassman-Beebe, PhD** Executive Vice President and Chief Development Officer Titan Pharmaceuticals, Inc.
	Clinical Safety	**Steve Chavoustie, MD** Segal Institute for Clinical Research

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DRAFT AGENDA (cont.)

	SPONSOR PRESENTATIONS (CONT.)	
	REMS	**Garry Neil, MD** Head of Research & Development Braeburn Pharmaceuticals, Inc.
	Conclusion	**Kate Glassman-Beebe, PhD**
9:50 a.m.	Clarifying Questions	
10:10 a.m.	**BREAK**	
10:25 a.m.	**FDA PRESENTATIONS**	
	Review of Probuphine Clinical Data: Efficacy and Safety	**Rachel Skeete, MD** Clinical Reviewer DAAAP, ODEII, OND, CDER, FDA
		David Petullo, MS Statistics Reviewer Division of Biostatistics II, Office of Biostatistics Office of Translational Sciences, CDER, FDA
11:20 a.m.	Contraceptive Implants: Regulatory History and Lessons Learned	**Barbara Wesley, MD, MPH** Clinical Reviewer Division of Reproductive and Urologic Products Office of Drug Evaluation III, OND, CDER, FDA
11:40 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**FDA PRESENTATIONS (CONT.)**	
	Risk Evaluation and Mitigation Strategy for Probuphine (15 min.)	**Jason Bunting, PharmD** Risk Management Analyst Division of Risk Management, Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology CDER, FDA
1:15 p.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	**BREAK**	
2:45 p.m.	**CHARGE TO THE COMMITTEE**	**Celia Winchell, MD**
2:50 p.m.	**QUESTIONS TO THE COMMITTEE/COMMITTEE DISCUSSION**	
5:00 p.m.	**ADJOURNMENT**	